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Dated: November 22, 2005 Signature: \_\_\_\_\_

Joseph A. Williams, Jr.

Docket No.: 31014/41515  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Goulet et al.

Application No.: 09/990,320

Filed: November 23, 2001

For: CONNECTIVE TISSUE SUBSTITUTES,  
METHOD OF PREPARATION AND USES  
THEREOF



Confirmation No.: 2528

Art Unit: 3738

Examiner: C. Prone

**PETITION TO WITHDRAW HOLDING OF FINALITY**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

The Applicants, through their undersigned attorney, hereby request reconsideration and withdrawal of the holding of finality with respect to the official action dated July 27, 2005. In the alternative, should the Examiner upon reconsideration decline to withdraw the finality of the action, this paper should be considered a petition to the Director pursuant to 37 CFR §§ 1.113(a) and 1.181 for such relief.

This paper is believed to timely filed as it is being submitted concurrently with request for a one-month extension of time. The Applicants understand that a petition pursuant to 37 CFR §1.181(f) not filed within two months of the mailing date of the action from which relief is requested *may* be dismissed as untimely, however should this paper be forwarded to the Director as a petition, the applicants request that the director consider the petition at his discretion or by suspension of the rules pursuant to 37 CFR §1.183.

## Statement of the Facts

The facts pertinent to this request/petition are as follows:

On January 7, 2005, a final office action was mailed wherein all prior rejections were rendered moot in view of amendments previously made by the Applicants.

The final action included one new ground for rejection of all pending claims under §102(e).

On April 7, 2005, the Applicants responded with no amendments to the claims but with argument against the only rejection.

The response at page 9 raised three points which distinguished the claimed invention from that disclosed in the prior art.

"Firstly, Altman does not disclose or suggest that 'laminin, fibronectin...', is in the form of a coating which is 'of sufficient thickness to allow for colonization by a cell' as recited in respect to the 'matrix layer' of instant claim 1.

Secondly, Altman does not disclose or suggest that 'laminin, fibronectin...' is 'dehydrated or lyophilized prior to implantation' as recited in respect to the 'matrix layer' of instant claim 1.

Thirdly, Altman does not disclose or suggest that 'laminin, fibronectin...' coats the 'cylindrical 3-dimensional matrix formed of collagen gel' which is considered analogous to the instant 'support filament' according to the above interpretation. Rather, Altman discloses that 'laminin, fibronectin...' may possible coat the 'anchor material'. Indeed, the suggested materials are proposed to 'enhance anchor attachment' (column 5, line 47 of Altman). Therefore, Altman does not disclose or suggest 'at least one matrix layer coating said support filament' as recited in instant claim 1."

On May 5, 2005, without a response from the examiner, the Applicants filed a request for continued examination (RCE).

The RCE included as a submission the response previously filed on April 7, 2005.

On July 19, 2005, the Patent Office, according to the Patent Office public PAIR website, received an Information Disclosure Statement (IDS) filed by the applicants.

On July 25, 2005, a first office action after the RCE issued wherein all claims were finally rejected.

In the response to the Applicants argument against the 102 rejection, the Examiner stated at pages 3-4 of the office action,

"...Contrary to Applicant's arguments, Altman does disclose laminin or fibrin that is sufficient thickness to allow for colonization by a cell. Applicants discloses in paragraph [0027] that their matrix is equivalent to a network of materials such as laminin or fibronectin. Applicant has not disclosed a specific thickness that is sufficient for colonization of cells therefore it is inherent that the matrix of Altman is capable of performing the function claimed by the Applicant. Altman also discloses that the matrix undergoes a dehydration or lyophilization process before implantation. Altman specifically discloses a 'dehydrothermal' process that includes dehydration (5:1-10). The Applicants arguments are unpersuasive."

The office action included a copy of the applicants' IDS, however none of the listed documents were initialed by the Examiner, nor did the office action indicate that copies of the listed references had not been received.

#### **Statement of the Applicable Rules**

A rejection of a claim may be made final on "the second or any subsequent examination or consideration by the examiner." 37 CFR § 1.113(a). A first action may be made final under certain limited circumstances. For example, an "action immediately subsequent to the filing of an RCE with a submission and fee under 37 CFR 1.114 may be made final only if the conditions set forth in MPEP § 706.07(b) for making a first action final in a continuing application are met." MPEP § 706.07(h), Part VIII (8<sup>th</sup> ed. Rev. 1, Feb. 2003). Section 706.07(b) states that:

The claims of a new application may be finally rejected in the first Office action in those situations where (A) the new application is a continuing application of, or a substitute for, an earlier application, and (B) all claims of the new application (1) are drawn to the same invention claimed in the earlier application, and (2) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. [Emphasis added.]

MPEP § 706.07(b) (8<sup>th</sup> ed. Rev. 1, Feb. 2003).

**Reasons for Granting the Requested Relief/Petition**

The Applicants' response on April 7, 2005, to the January 7, 2005 office action included an argument against the only rejection under §102(e) wherein three points were raised which distinguished the claimed invention from that disclosed in art ("Altman") cited by the Examiner. There is no evidence that the Applicants received an Advisory Action indicating that the April 7, 2005, response had been entered into the file.

On May 5, 2005, the Applicants filed an RCE which included as a submission the response that was filed on April 7, 2005; both submissions including the same three points distinguishing the claimed invention from the art. On July 25, 2005, the Patent Office issued a first action final rejection of all claims, wherein the Examiner addressed only two of the points of distinction raised by the applicants in the May 5, 2005 response.

To wit, on the first point, the Applicants stated,

"Firstly, Altman does not disclose or suggest that 'laminin, fibronectin...' is in the form of a coating which is 'of sufficient thickness to allow for colonization by a cell' as recited in respect to the 'matrix layer' of instant claim 1.

The Examiner addressed this point stating,

Contrary to Applicant's arguments, Altman does disclose laminin or fibrin that is sufficient thickness to allow for colonization by a cell. Applicants discloses in paragraph [0027] that their matrix is equivalent to a network of materials such as laminin or fibronectin. Applicant has not disclosed a specific thickness that is sufficient for colonization of cells therefore it is inherent that the matrix of Altman is capable of performing the function claimed by the Applicant.

On the second point, the Applicants stated,

Secondly, Altman does not disclose or suggest that 'laminin, fibronectin...' is 'dehydrated or lyophilized prior to implantation' as recited in respect to the 'matrix layer' of instant claim 1.

The Examiner responded, stating,

Altman also discloses that the matrix undergoes a dehydration or lyophilization process before implantation. Altman specifically discloses a 'dehydrothermal' process that includes dehydration (5:1-10).

On the third point, the Applicants stated,

Thirdly, Altman does not disclose or suggest that 'laminin, fibronectin...' coats the 'cylindrical 3-dimensional matrix formed of collagen gel' which is considered analogous to the instant 'support filament' according to the above interpretation. Rather, Altman discloses that 'laminin, fibronectin...' may possible coat the 'anchor material'. Indeed, the suggested materials are proposed to 'enhance anchor attachment' (column 5, line 47 of Altman). Therefore, Altman does not disclose or suggest 'at least one matrix layer coating said support filament' as recited in instant claim 1."

The Examiner, however, did not address this distinction, having simply concluded the rebuttal remarks after addressing the applicants' second point by stating, "The Applicants arguments are unpersuasive."

While not admitting that the Examiner's rebuttal arguments are correct with respect to the first and second points raised by the Applicants, the Applicants submit that the Examiner's position with respect to the first two points raised by the Applicants were made clear. However, the Examiner's failure to address the third point raised by the Applicants with any argument or facts in rebuttal may be construed as an admission on the part of the Examiner that this third distinction is accurate, the novelty rejection cannot be sustained, and the claims are allowable. It is therefore unclear whether the examiner simply dismissed or inadvertently overlooked the Applicants' third point, but whatever the reason, the Applicants have no recourse except to raise the same issue again, but now after final rejection.

Moreover, according to 37 CFR §706.07(b) a final rejection may be proper if all claims of the new application would have been properly finally rejected on the grounds and art of record in the next office action if they had been entered in the earlier application. In the present application, subsequent to the above-mentioned RCE filed on May 5, 2005, and prior to the final office action dated July 25, 2005, the Applicants filed an IDS which was received in the Patent Office on July 19, 2005. In the final office action of July 25, 2005, a copy of the IDS was returned to the Applicants but none of the listed references were initialed by the Examiner, and no reason was provided in the office action which explained why the listed documents had not been considered. Because the IDS submission made of record all documents referred to therein, the Examiner could not state that all requirements of Section 706.07(b) were met.

In view of the foregoing, it is respectfully submitted that the finality of the July 25, 2005, action is premature.

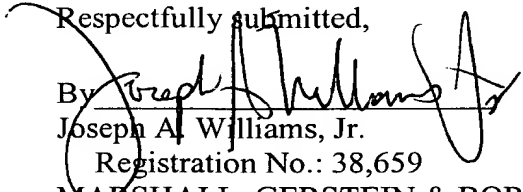
### **Conclusion**

In the interest of providing the Applicants with a full and fair consideration of their claims, the applicants, through their undersigned attorney, hereby request reconsideration and withdrawal of the holding of finality of the July 25, 2005, official action. Upon reconsideration, should the Examiner decline to withdraw the finality of the outstanding action, this paper should be considered a petition to the director for such relief.

Any required petition fee (e.g., a \$130 petition fee pursuant to 37 CFR § 1.17) for petition to the direct and/or suspension of the rules may be charged to our Deposit Account No. 13-2855. A copy of this paper is enclosed.

Dated: November 23, 2005

Respectfully submitted,

By   
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